

INDIANA IMMUNIZATION PROGRAM
STATEMENT OF POLICY
External Policy

Title of Policy: **Vaccine Cold Chain Failure:
Procedures and Corrective Action**

Policy Number:
II-09 (1/2009)

Effective Date: February 18, 2009

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Purpose: This policy defines procedures and corrective actions that should be followed to resolve vaccine cold-chain failures resulting from improper shipping, transfer or storage. Failure to maintain the cold-chain of vaccines due to shipping delays, power outages, equipment failure and human error may cause vaccines to become ineffective. Vaccines must be stored properly from the time they are manufactured until the time they are administered. If any vaccine is determined to have exceeded the established temperature ranges or storage and handling requirements the following actions should be implemented immediately:

- Correct improper storage and handling conditions including exposure to light and storage temperatures that are outside of the established range.
- Check all thermometers for correct placement and operation. Document any temperature fluctuation and the amount of time that vaccines were out of the correct temperature range.
- If vaccine shipping or storage temperatures are recorded **above** or **below** the required range, do not use the vaccine until the viability of the vaccine has been established by the vaccine manufacturer. Place the vaccine in the refrigerator or freezer, depending on the proper storage requirements, and clearly mark the vaccine "Not for Use".
- If necessary, move vaccines to a pre-established back-up location to maintain the cold-chain.
- If vaccines are determined to have exceeded designated shipping or storage temperatures, providers must contact the manufacturer and obtain guidance and recommendations for vaccine viability. If vaccines are determined to be non-viable by the manufacturer providers will contact the ISDH, Immunization Program to arrange for the return of the non-viable vaccine to the McKesson shipping facility. Providers should never discard or return any vaccine unless they are instructed to do so by the ISDH, Immunization Program.
- Report all incidents of vaccine cold-chain failure within 24 hours to the state Immunization Program Field Representative in your region or call the Indiana State Department of Health's Immunization Program at 1-800-701-0704.

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- Providers must also complete a *VFC Incident Report* within three (3) business days of the incident and submit by fax it to:

VFC Coordinator
VFC Incident Report
ISDH, Immunization Program
FAX: (317) 233-3719
Telephone: 1-800-701-0704

- Shipping boxes containing publicly provided vaccines must be opened and inspected immediately after receipt. Check all vaccines, enclosed temperature monitors and shipping invoices. If vaccines have been compromised or if the temperature monitors are out of range, the provider must immediately contact the Indiana State Department of Health's Immunization Program at 1-800-701-0404 to report the incident. The State Immunization Program is required to notify McKesson within two hours of a provider receiving a compromised vaccine shipment in order to receive proper vaccine reimbursement and credit.
- Participation in the Vaccines for Children Program requires that each facility must have written emergency procedures for the proper handling of publicly provided vaccines in the event of power or equipment failure. See ***Procedural Guidelines for Emergency Management of Vaccines***, Policy II-02 (R2-7/2006), Attachment A.
- If publicly provided vaccine is damaged due to negligence, abuse or human error, providers may be required to reimburse the ISDH Immunization Program for the cost of the damaged vaccines. Refer to ***Recovery of Funds for Damaged Public Vaccines***, Policy II-03 (R2-7/2006).

Approved by:  Date: February 18, 2009
Joan Duwve, M.D., MPH, Medical Director, ISDH

Policy Review Log:

Initials						
Date	2/18/2009					